

# Treatment of duck-phenotype keratoconus using asymmetric intrastromal corneal ring-segments with hybrid technique

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## Conflict of interest

The authors declare that they have no affiliations with or involvement in any organization or entity with any financial interest in the subject matter or materials discussed in this manuscript.

## Abstract

**Objective:** To evaluate the safety and efficacy of using asymmetric intrastromal corneal ring-segments (ICRS) for the treatment of duck-phenotype keratoconus through an hybrid technique.

**Methods:** A retrospective study was performed in a private clinic of Cordoba City (Argentina), evaluating patients with duck-phenotype keratoconus, implanted with one segment of Keraring AS6 (Mediphacos, Belo Horizonte, Brazil). Uncorrected distance visual acuity (UDVA), manifest refractive spherical equivalent (MRSE), manifest refractive astigmatism, and topographic parameters were evaluated before and six months after the procedure.

**Results:** 31 eyes of 27 patients received Keraring AS6 implants, attaining a reduction in median UDVA from 0.7 to 0.3, mean keratometry from  $47.39 \pm 2.75$  D to  $45.45 \pm 2.97$  D, median refractive astigmatism from -5.00 D to -2.50 D and MRSE from -5.25 D to -2.62 D. All effects were statistically significant ( $p < 0.01$ ).

**Conclusions:** In the present series, Keraring AS6 implantation by hybrid technique was effective and safe for correcting corneal irregularities secondary to duck-phenotype keratoconus, improving UDVA, MRSE, manifest astigmatism, and topographic parameters.

**Keywords:** keratoconus, corneal topography, corneal diseases, corneal pachymetry.

## Tratamiento del queratocono con fenotipo de pato utilizando anillos-segmentos corneales intraestromales asimétricos mediante una técnica híbrida

### Resumen

**Objetivo:** Evaluar la seguridad y eficacia del uso de anillos-segmentos corneales intraestromales asimétricos (ICRS) para el tratamiento del queratocono de fenotipo pato mediante una técnica híbrida.

**Materiales y métodos:** Se realizó un estudio retrospectivo en una clínica privada de la ciudad de Córdoba (Argentina), evaluando pacientes con queratocono de fenotipo pato, implantados con un segmento de Keraring AS6 (Mediphacos, Belo Horizonte, Brasil). Se evaluaron la agudeza visual a distancia sin corrección (AV/sc), el equivalente esférico refractivo manifiesto (EERM), el astigmatismo refractivo manifiesto y los parámetros topográficos antes y seis meses después del procedimiento.

**Resultados:** 31 ojos de 27 pacientes recibieron implantes Keraring AS6, consiguiendo una reducción de la UDVA mediana de 0,7 a 0,3, de la queratometría media de  $47,39 \pm 2,75$  D a  $45,45 \pm 2,97$  D, del astigmatismo refractivo medio de  $-5,00$  D a  $-2,50$  D y del MRSE de  $-5,25$  D a  $-2,62$  D. Todos los cambios fueron estadísticamente significativos ( $p < 0,01$ ).

**Conclusiones:** En la presente serie el implante de Keraring AS6 mediante técnica híbrida resultó eficaz y seguro para corregir las irregularidades corneales secundarias al queratocono de fenotipo pato, mejorando la AV/sc, el EERM, el astigmatismo manifiesto y los parámetros topográficos.

**Palabras clave:** queratocono, topografía corneal, enfermedades corneales, paquimetría corneal.

## Tratamento do ceratocone com fenótipo de pato usando anéis-segmentos intraestromais assimétricos da córnea por uma técnica híbrida

### Resumo

**Objetivo:** Avaliar a segurança e a eficácia do uso de segmentos de anéis corneanos intraestromais assimétricos (ICRS) para o tratamento do ceratocone tipo pato usando uma técnica híbrida.

**Materiais e métodos:** Foi realizado um estudo retrospectivo em uma clínica privada na cidade de Córdoba (Argentina), avaliando pacientes com ceratocone de fenótipo de pato, implantados com um segmento Keraring AS6 (Mediphacos, Belo Horizonte, Brasil). A acuidade visual à distância não corrigida (AU/sc), o equivalente esférico refrativo manifesto (MRSE), o astigmatismo refrativo manifesto e os parâmetros topográficos foram avaliados antes e seis meses após o procedimento.

**Resultados:** 31 olhos de 27 pacientes receberam implantes Keraring AS6, obtendo uma redução na UDVA mediana de 0,7 para 0,3, ceratometria média de  $47,39 \pm 2,75$  D para  $45,45 \pm 2,97$  D, astigmatismo refrativo médio de  $-5,00$  D para  $-2,50$  D e MRSE de  $-5,25$  D para  $-2,62$  D. Todas as alterações foram estatisticamente significativas ( $p < 0,01$ ).

**Conclusões:** Na presente série, o implante de Keraring AS6 usando uma técnica híbrida foi eficaz e seguro na correção de irregularidades da córnea secundárias ao ceratocone tipo pato, melhorando VA/sc, EERM, astigmatismo manifesto e parâmetros topográficos.

**Palavras-chave:** ceratocone, topografia da córnea, doenças da córnea, paquimetria da córnea.

### Introduction

Keratoconus is a non-inflammatory corneal ectatic disease<sup>1</sup>. Their pathophysiology is complex and not yet fully understood, but it is known to be multifactorial<sup>2-3</sup>.

According to the Fernandez-Vega/Alfonso classification, keratoconus can be classified into five distinct morphological phenotypes using topography in accordance with the centralization and coincidence of the flat and comatic axes<sup>4</sup>. The “nipple” phenotype occurs with a central and hyperprolate ectasia; the “bowtie” phenotype occurs with central regular astigmatism; the “croissant” phenotype occurs when the ectasia is paracentral and the comatic and topographic astigmatism axes coincide; the “duck” phenotype occurs when the ectasia is paracentral and the astigmatism and comatic axes do not coincide; and the “snowman” phenotype occurs when the ectasia is paracentral and axes are perpendicular.

Several treatment modalities are available for different stages of keratoconus. Intrastromal corneal ring segments (ICRS) implantation is a safe, minimally invasive, and reversible option to modify the shape of the cornea, flattening the central region due to an arc effect caused by peripheral thickening<sup>5</sup>. ICRS were initially developed for the treatment of myopia, but gained much more relevance in the treatment of keratoconus over time<sup>6-7</sup>.

A conventional ICRS is a fixed thickness segment that is usually implanted symmetrically in the cornea. However, in 21% to 60% of keratoconus cases in clinical practice<sup>8</sup>, there is a significant difference between the comatic and topographic astigmatism axes; therefore, the necessary flattening for corneal regularization is different for each area of the cornea. Recently, progressive thickness ICRS (PT-ICRS) Keraring AS6 (Mediphacos Ltd., Belo Horizonte, Brazil) has been developed. Keraring AS6 features segments with variable thickness, progressing from a thinner area to a thicker one, usually starting from 150 to 200  $\mu\text{m}$  and progressing up to 300  $\mu\text{m}$  and length of 160°. This technology enables focal and individualized structural modifications of the cornea<sup>9</sup>.

This study aimed to evaluate the clinical results of a single Keraring AS6 PT-ICRS implant with a 6 mm optic zone (AS6) in patients with duck-phenotype keratoconus, who present a marked difference between the comatic and topographic astigmatism axes, and therefore may have greater benefit from the individualization of corneal remodeling.

## Materials and methods

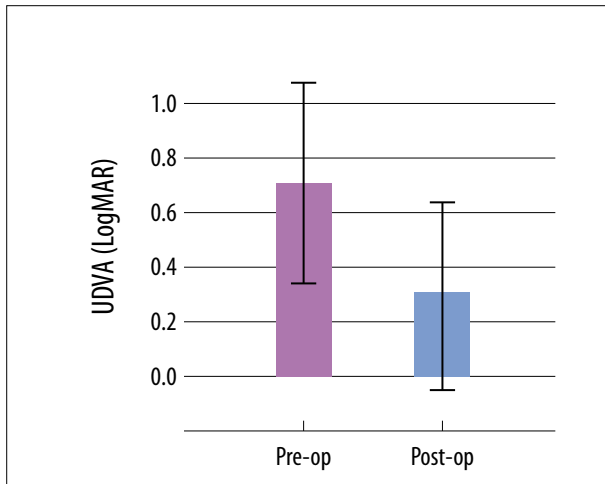
An unicentric non-masked retrospective case-series study was designed, for review clinical records of patients with duck-phenotype keratoconus who underwent implantation of a single Keraring AS6 PT-ICRS, at Clinica de Ojos Córdoba (Córdoba City), Argentina. The tenets of the declaration of Helsinki were followed and the study was conducted with full ethical approval from the institutional review board. All patients received a clear and complete explanation of the procedures and possible consequences of the surgery, and signed an informed consent form.

Clinical records of individuals with duck-phenotype keratoconus, aged 15 to 35 years, who had a demand for improvement in visual acuity or intolerance to contact lenses, with stages I to III according to the Amsler-Krumeich classification, visual acuity (LogMAR) worse than 0.2, maximum keratometry (K) inferior to 64 diopters, clear central cornea, and minimum corneal thickness of 400  $\mu\text{m}$  in the path of the ICRS were included in the study. Patients with a history of herpes, glaucoma, cataracts, uveitis, retinopathies, or other active ocular or systemic comorbidities with a potential impact on study variables were excluded.

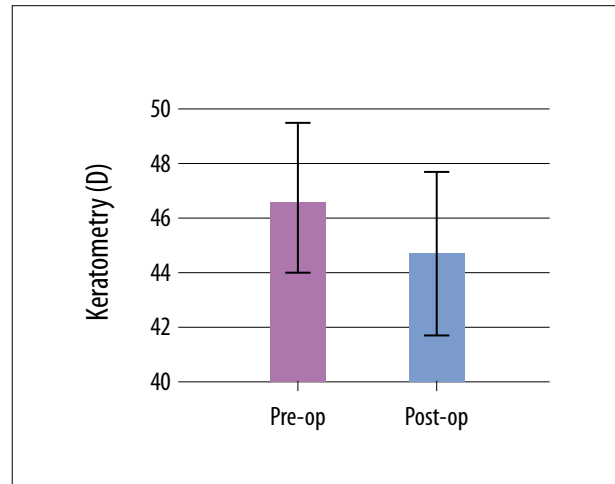
Keraring AS6 is a polymethylmethacrylate (PMMA) implant that is triangular in shape, 6 mm in diameter in the optic zone and 160° of length, presenting a thinner region (150  $\mu\text{m}$  or 200  $\mu\text{m}$ ) that becomes progressively thicker until it reaches 250  $\mu\text{m}$  or 300  $\mu\text{m}$ . In our case, when astigmatism was greater than 5.00 D, a Keraring AS6 160° 200-300  $\mu\text{m}$  segment was implanted, and when astigmatism was lesser than 5.00 D, a Keraring AS6 160° 150-250  $\mu\text{m}$  segment was implanted.

All surgeries were performed by a single experienced surgeon (B.C.A.). The surgical procedure was performed under sterile conditions and topical anesthesia. The horizontal axis was marked before surgery with the patient sitting upright. The optical axis was marked according to the Purkinje reflex using a Sinskey hook and a methylene blue marker. The steepest corneal meridian was marked using a 5 mm double optical marker, which also marked the exact ring tunnel trajectory. Using a diamond blade knife, the initial incision was made on the steepest meridian at 80% depth of the thinnest corneal thickness of the tunnel. Tunnels were made using a hybrid technique, placing a vacuum pump after pocketing the incision site, activating it, and creating the tunnel with a corneal dissector under negative pressure; once the tunnel was made, the pressure of the vacuum pump was released, the suction ring was removed, and a single PT-ICRS was implanted, with the thinnest end of the ICRS near the incision and the center of the implant aligned with the flattest meridian.

A soft contact lens bandage was applied for 24 h after surgery. Patients were prescribed topical moxifloxacin 0.5% and dexamethasone 0.1% four



**Figure 1.** Uncorrected distance visual acuity (UDVA), preoperative and 6 months after surgery.



**Figure 2.** Keratometry outcomes, preoperative and 6 months after surgery.

times daily for seven days and lubricant eye drops four times daily.

Postoperative visits were made on days 1, 7, 30, 90, 180, and 365. Each evaluation included uncorrected distance visual acuity (UDVA), manifest refraction, slit-lamp biomicroscopy, and keratometry. The results presented were obtained from the measurements on postoperative day 180.

Data analysis was performed using Python 3.9.5 and the most recent stable versions of the NumPy, SciPy, and Pandas libraries. Normality was checked using the Kolmogorov-Smirnov test and QQ plots. Descriptive statistics (mean, median, standard deviations, and frequency) were calculated for all the variables. Correlations were defined using Spearman's  $r$  test. Normally distributed continuous variables before and after surgery were compared using paired Student's  $t$ -test, whereas non-normally distributed variables were compared using Wilcoxon signed-rank test. Differences were considered statistically significant when the  $p$ -value was  $<0.05$ .

## Results

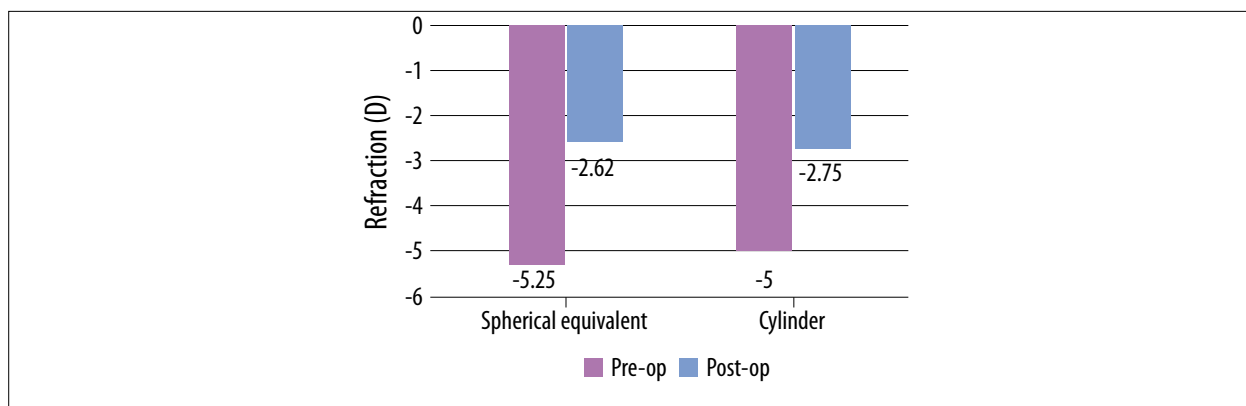
The sample consisted of 31 eyes of 27 patients with duck-phenotype keratoconus, with a mean age of  $27.7 \pm 6.2$  years and 56.66% being female.

Statistically significant correlations ( $p < 0.01$ ) were found between preoperative mean, flat, and steep K readings and postoperative UDVA ( $r = 0.66$  to  $0.72$ ), postoperative manifest refractive spherical equivalent (MRSE) ( $r = 0.41$  to  $0.49$ ). There was also a significant correlation between preoperative and postoperative UDVA ( $r = 0.74$ ), and between preoperative MRSE and postoperative UDVA ( $r = 0.69$ ).

The preoperative median UDVA was 0.7 (LogMAR), and the postoperative median was 0.3 (Fig. 1), representing a statistically significant difference ( $p < 0.01$ ) (Table 1). No patient lost lines of UDVA; however, of the 31 eyes, four (12.9%) showed no improvement in UDVA after the procedure.

The preoperative K reading in the flat axis had a mean value of  $45.36 \pm 2.50$  D (standard deviation). In the steep axis, the preoperative K reading had a mean value of  $49.42 \pm 3.26$  D. The mean preoperative K reading was  $47.39 \pm 2.75$  D. In the postoperative evaluation, the mean K readings for the flat axis were  $44.21 \pm 2.85$  D, for the steep axis were  $46.70 \pm 3.16$  D and for mean K readings were  $45.45 \pm 2.97$  D. The differences between all the groups were statistically significant ( $p < 0.01$ ) (Fig. 2).

Median refractive astigmatism was  $-5.00$  D before surgery and  $-2.50$  D after the procedure.



**Figure 3.** Spherical equivalent and cylinder values, preoperative and 6 months after surgery.

**Table 1.** Preoperative versus 12 months visual, refractive and topographic outcomes.

	Pre-op	12 months	p-value
UDVA (LogMAR)	0.7 <sup>+</sup>	0.3 <sup>+</sup>	< 0.01
Mean Keratometry (D)	47.39*	45.45*	< 0.01
Cylinder (D)	-5.00 <sup>+</sup>	-2.75 <sup>+</sup>	< 0.01
Spherical Equivalent (D)	-5.25 <sup>+</sup>	-2.62 <sup>+</sup>	< 0.01

<sup>+</sup>Medians compared by Wilcoxon signed-rank test. \*Means compared by paired Student's t test.

The median MRSE was -5.25 D before surgery and -2.62 after the procedure (Fig. 3). The difference was statistically significant for both the parameters ( $p < 0.01$ ).

No severe complications were observed intraoperatively or postoperatively. No infections occurred, and no rings have been explanted until the end of the follow-up. There was no corneal melting or perforation reported. One patient had a slightly displaced ring, but it did not require repositioning because the vision and topographic parameters were not modified.

## Discussion

This study evaluated the clinical results of Keraring AS6 implantation in patients with duck-phenotype keratoconus, as described by

Alfonso in 2014, which consists of irregular paracentral astigmatism with misaligned comatic and astigmatic axes<sup>4</sup>. This phenotype presents additional challenges for surgical planning, and is a possible indication for PT-ICRS.

Our study demonstrated the safety and efficacy of implanting a single segment of Keraring AS6 in patients with duck-phenotype keratoconus, achieving a significant reduction in topographic and refractive parameters and an important improvement in visual acuity. Next, we compared the results obtained in this study with those available in the literature, emphasizing that it was not possible to perform a statistically accurate comparison using available data. Nevertheless, this analysis provides valuable input for the use of PT-ICRS.

Several studies have described the effects of conventional ICRS implantation in the treat-

ment of different keratoconus phenotypes. Alfonso *et al.* observed in 2012 that the implantation of Ferrara rings (AJL Ophthalmic, Vitoria-Gasteiz, Spain) in croissant phenotype keratoconus improved the UDVA from 0.77 to 0.38 after 6 months, which is consistent with our study<sup>10</sup>. A study by Alfonso *et al.* conducted in 2013, obtained modest results, with an improvement from 0.76 to 0.53<sup>11</sup>. Fernández-Vega Cueto *et al.* conducted a study in 2016 in which Ferrara rings were implanted in 409 eyes and observed an improvement in UDVA from 0.72 to 0.37, which is consistent with the results of other studies<sup>12</sup>. In addition, he observed a reduction in MRSE from -4.16 to -2.81 D, a smaller reduction than that obtained in our study, and in refractive astigmatism from -4.19 to -1.75, similar to the obtained in this study. The authors did not observe a significant reduction in the minimum K readings (44.11 to 44.62), but obtained a reduction in the maximum K readings from 48.23 to 46.31, which is less expressive than those obtained in our study. Another study developed by Fernández-Vega Cueto *et al.* obtained an average improvement in UDVA of 0.18<sup>13</sup>. Although this number was smaller than that attained in our study, it is important to consider that both groups had an initially higher UDVA than ours. A reduction in MRSE of 0.51 D and refractive astigmatism of approximately 1 D were also observed. The mean reduction in K readings was 0.51 D for minimum readings and 0.79 D for maximum readings, results similar to those of the 2016 study by the same author.

Despite being a recent technology, several clinical studies have been conducted on the PT-ICRS implants. Keraring AS implants were analyzed in several studies, with single or double implants and with different optical zones, with, in most cases, congruent results to those obtained in this study. This demonstrates the effectiveness of Keraring AS in the treatment of keratoconus, especially those with duck, snowman, and croissant phenotypes, which are the most commonly addressed in these studies.

Coskunseven *et al.* observed a mean improvement in UDVA from 0.71 to 0.28, a reduction in refractive astigmatism from -4.15 to -2.35 D, and a reduction in maximum K readings from 54.21

to 50.93 D<sup>14</sup>. When differentiating participants by phenotype, the most marked effect on UDVA was observed in the snowman phenotype (0.78 to 0.18) and the smallest in the croissant phenotype (0.68 to 0.30). However, only five participants had a snowman phenotype; thus, these findings require confirmation in samples with greater statistical power. Coskunseven and Kayhan carried out another study with the implantation of Keraring AS in patients with duck-phenotype keratoconus, observing an improvement in UDVA from  $0.85 \pm 0.36$  to  $0.27 \pm 0.14$ , in MRSE from  $-3.66 \pm 2.60$  D to  $-1.60 \pm 1.42$  D and in refractive astigmatism from  $-4.91 \pm 2.65$  D to  $-1.41 \pm 1.31$  D<sup>15</sup>. Arbelaez and Arbelaez implanted Keraring AS in patients with duck-phenotype keratoconus, obtaining an improvement in UDVA from 0.70 to 0.22, in MRSE from -2.70 D to -0.80 D and in maximum K readings from 53.7 D to 48.7 D<sup>16</sup>. Baptista *et al.* implanted Keraring AS in patients with duck and snowman phenotype keratoconus, comparing both subtypes<sup>17</sup>. The UDVA of patients with duck-phenotype keratoconus changed from 1.4 to 0.27, while patients with snowman phenotype changed from 0.65 to 0.43, in contrast with what was observed by Coskunseven *et al.*, with stronger results than those of other studies<sup>14</sup>. The reduction in maximum K readings in this study was also more pronounced in the duck phenotype group (57.17 to 53.94 D) than in the snowman phenotype group (55.46 to 53.38 D). MRSE and refractive astigmatism were similar in both groups. Prisant *et al.* performed the Keraring AS implant in patients with keratoconus, without differentiation by phenotype, and observed an improvement in UDVA from 0.82 to 0.46, in refractive astigmatism from -4.22 D to -2.01 D, in MRSE from -3.85 D to -1.91 D, and in the maximum K readings from 53.6 to 50.3 D, results comparable to those of the present study<sup>8</sup>.

Barugel *et al.*, on the other hand, did not find significant advantages when comparing the PT-ICRS implantation to common ICRS, except with the implantation of two asymmetrical segments in relation to the symmetrical ones, which reduced the vertical asymmetry and prevented increases in corneal aberration in snowman patterns<sup>18</sup>.

Other devices with progressive thickness have also been presented. Visumring is a ring segment

with a 353° arc and an internal diameter of 5.5 mm, and a thickness ranging from 150 to 350 µm. Vega-Estrada *et al.* implanted Visumring in patients with keratoconus in an asymmetric bowtie pattern, obtaining a reduction in UDVA from 1.09 to 0.65, in MRSE from -12.38 to -5.00 D and in mean K readings from 51.8 to 47.6 D<sup>19</sup>. The results obtained were more intense than those achieved in the present study. However, it is important to highlight that the study by Vega-Estrada *et al.* included patients with more advanced cases of keratoconus, which are normally not included in other studies and present more room for drastic improvement<sup>19</sup>.

The AJL-pro+ PT-ICRS (AJL Ophthalmic, Vitoria-Gasteiz, Spain) was derived from a traditional Ferrara ring to maintain the original triangular cross-sectional design. Kammoun *et al.* implanted PT-ICRS AJL-pro+ with a 6 mm optic zone and 150-250 µm or 150-300 µm thickness in 35 eyes with keratoconus presenting with incongruent comatic and topographical axes, obtaining a reduction in MRSE from -5.05 to -2.54 D and refractive astigmatism from -4.14 to -1.66 D, results comparable to those obtained in this study, as well as a reduction in mean K readings from 46.50 to 44.98 D, which was lower than that obtained in this study<sup>20</sup>.

The results of this study, which are comparable to most studies using either manual or femtosecond-assisted laser tunneling, also demonstrate that using a suction ring during corneal dissection allows safe and efficient corneal stroma tunnelization, achieving the desired depth and centration and thus avoiding the excessive and traumatic movement generated by the manual technique without a vacuum pump<sup>8, 10-18</sup>.

Different treatment strategies for irregular paracentral keratoconus phenotypes have also been developed. Fernández-Vega-Cueto *et al.* compared implantation of Ferrara rings in the comatic axis versus the flat axis in patients with perpendicular comatic and astigmatic axes<sup>13</sup>. The authors observed better results with implants centered on the comatic axis. Such an approach can be challenging for the duck phenotype, because the alignment of the axes is widely variable, possibly generating unpredictable results. It is possible that the superior customization capacity of the PT-ICRS

may generate better results in these cases. The present study demonstrated the safety and efficacy of the Keraring AS6 implant in patients with keratoconus “duck” phenotype following the traditional alignment strategy, which aligns the thickest segment region with the flat axis. Future studies are needed to validate the Keraring AS implant by using different alignment strategies.

The present study evaluated the efficacy and safety of Keraring AS6 in a population with duck-phenotype keratoconus and demonstrated positive results. The limitations of this study include the small sample size, relatively short follow-up period, evaluation of only topographic and refractive parameters, absence of a control group, and randomization and blinding methods.

In conclusion, in the present series, Keraring AS6 implantation by hybrid technique was effective and safe for correcting corneal irregularities secondary to duck-phenotype keratoconus, improving UDVA, MRSE, manifest astigmatism, and topographic parameters. More controlled, randomized, and blinded clinical studies are needed to adequately evaluate the effects of PT-ICRS in keratoconus, with larger sample sizes, longer follow-up periods, different implant strategies, and the evaluation of multiple topographic, tomographic, and aberrometric parameters.

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